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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/064,000	04/21/1998	JAMES P. ELIA	796-P-12	5311

7590 10/18/2004

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/064,000

Applicant(s)

ELIA, JAMES P.

Examiner

Elizabeth C. Kemmerer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 382-388 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 382-388 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment filed 19 August 2004 has been entered in full. Claims 1-381 are canceled. Claims 382-388 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The requirement for a new title as set forth at p. 4 of the previous Office Action (mailed 03 June 2004) is *withdrawn* in view of the new title submitted by Applicant (19 August 2004).

All objections and rejections of claims 192, 193, 195-199, 211, 213-225, 227, 243-251, 253, 254, 256-260, 272, 274-286, 288, 304-312, 314, 315, 317-321, 333, 335-348, 350, 366-374 and 376-381 are *withdrawn* in view of the canceled claims.

Election/Restriction

Applicant argues that a new restriction requirement was made in the previous Office Action (mailed 03 June 2004) when species o) and q) of Part I were rejoined to species c) of Part I. This has been fully considered but is not found to be persuasive. Rejoinder of species or Groups after a restriction requirement is, in fact, a withdrawal in part of the restriction requirement, not a new restriction requirement.

Applicant reviews the restriction history of the application. Applicant asserts that a fourth restriction was imposed on 03 June 2004 on the basis of a newly provided interpretation of "living organism." Applicant argues that the interpretation was made for the first time and is at odds with Applicant's intended interpretation. Applicant complains that it has been more than three years since submitting a response on the merits, and that Applicant is now faced with resolution of formal matters. This has been fully considered but is not found to be persuasive. No new restriction was made in the previous Office Action. The interpretation of what is meant by "living organism" was gleaned from references, which were cited in the previous Office Action. Such is entirely proper. Although the delay in prosecution is regretted, this examiner has always acted on the instant application with dispatch. The suspensions imposed by the previous examiner were not within the current examiner's control.

Applicant argues that the alleged latest restriction was interpreted by the examiner to exclude multifactorial and non-specific living organisms and essentially restrict the interpretation to bacteria and viruses. This has been fully considered but is not found to be persuasive. The examiner did not place an improper interpretation upon the elected invention. References were provided to define "living organism." Such is not limited to bacteria and viruses, but also includes multicellular living organisms.

Applicant traverses the alleged new restriction requirement on the grounds that Applicant intended "living organism" to include multifactorial and non-specific living organisms, such as stem cells. Applicant urges that claims 376-381 indicated that Applicant intended to prosecute claims directed to growth factors comprising

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multifactorial and non-specific living organisms. Applicant refers to the specification as supporting the idea that growth factors can be multifactorial and non-specific cells. This has been fully considered but is not found to be persuasive. Stem cells are not living organisms. They are parts of a living organism. As discussed in the previous Office Action, living organisms exist independently. Stem cells do not exist independently.

Applicant argues that stem cells are living organisms. Applicant reasons that stem cells are clonogenic and that clones are living organisms. Applicant provides definitions of clones. This has been fully considered but is not found to be persuasive. The term "clone" can refer to pieces of nucleic acid, cells or entire living organisms. Cells, while alive, are not necessarily a living organism. Living organisms must be independent. See references cited in previous Office Action.

Applicant argues that the term "multifactorial and non-specific" is used in the specification to characterize a type of growth factor rather than causes, effects, and processes. Applicant argues that the Office Action is incomplete because the examiner's interpretation was erroneous and inconsistent with Applicant's intended election. This has been fully considered but is not found to be persuasive. While the specification states that "multifactorial and non-specific growth factors" are intended, the specification does not explain what these terms mean with reference to growth factors. The art only uses the terms to describe causes, effects, and processes, as explained in the previous Office Action. However, this is an issue under 35 U.S.C. § 112, second paragraph, not restriction. The Office Action was not incomplete because the examiner's interpretation was not erroneous. References were cited to support the

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examiner's interpretation of the term "living organism." None of the previous pending claims recited "stem cells." Therefore, it is difficult to envision how the examiner could have been expected to understand that this was Applicant's intended elected invention.

Claims 382-388 are under examination to the extent they read on the elected invention of a method for producing a desired soft tissue in a body of a human patient comprising: (a) placing a living organism in said body of said human patient; (b) forming a bud in said body of said human patient; and (c) growing said desired soft tissue from said bud.

Claim Objections

Claims 382-388 are objected to because of the following informalities: the claims read on non-elected inventions. Appropriate correction is required.

35 U.S.C. § 112, Second Paragraph

Claims 383 and 384 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The basis for this rejection is the same as that set forth at p. 5 of the previous Office Action (mailed 03 June 2004) regarding the meaning of the term "multifactorial and non-specific" as applied to a living organism.

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Applicant's arguments (pp. 7-8, amendment of 19 August 2004) have been fully considered but are not found to be persuasive for the following reasons. Applicant argues that the term "multifactorial and non-specific" has been used in the specification to characterize living organisms, such as stem cells, and not do describe causes, effects and processes as allegedly incorrectly premised by the examiner. This has been fully considered but is not found to be persuasive. As discussed in the previous Office Action, the specification connects the phrase "multifactorial and non-specific" to growth factors, but does not explain what is meant by such. Despite significant searching of the literature databases by the examiner, no art was found that uses the term "multifactorial and non-specific" to describe any cells or living organisms. The art only uses the term to describe causes, effects and processes. No evidence has been brought forth on the record to contradict this finding. Furthermore, stem cells are not living organisms. Stem cells can be found within multicellular living organisms. Stem cells are a part of a living organism, but are not living organisms *per se*. Multiple references have been cited on the record to support that the art views stem cells as a part of a living organism, and that the art defines "living organism" as independent. While Applicant may be his own lexicographer, to define a living organism as encompassing stem cells is repugnant to the meaning of "living organism" found in the art. Such is improper.

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35 U.S.C. §§ 101 and 112, First Paragraph

Claims 382-388 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

Claims 382-388 are rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The basis for this rejection is the same as that set forth at pp. 6-13 of the previous Office Action (mailed 03 June 2004).

Applicant argues that the rejection is premised on what Applicant believes to be the examiner's allegedly incorrect and improper interpretation of "living organism," i.e., that such term is limited to bacteria and viruses and does not include cells. Applicant urges that the rejection does not apply to the newly submitted claims. This has been fully considered but is not found to be persuasive. "Living organisms" is not being interpreted as being limited to bacteria and virus. "Living organism" also applies to multicellular life forms which are composed of cells. "Living organisms" does not encompass isolated stem cells, as discussed above. Therefore, the instant claims, as they read on the elected invention of methods of administering living organisms to achieve production of a desired soft tissue in a human, are rejected for lack of utility and enablement for the reasons of record.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D. can be reached on (571) 272-0961. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ECK

Elizabeth C. Henneman

ELIZABETH C. HENNEMAN
PATENT EXAMINER